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PFIZER INC.

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN FRANCISCO DIVISION

18 IN RE BEXTRA AND CELEBREX
19 MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

20 *This document relates to*

21 ERIK B. CHERDAK,

22 Plaintiff,

23 vs.

24 PFIZER INC.,

25 Defendant.
26
27
28

) MDL Docket No. 1699

) CASE NO. 3:08-cv-2477-CRB

) **PFIZER INC.'S ANSWER TO
COMPLAINT**

) **JURY DEMAND ENDORSED
HEREIN**

1 NOW COMES Defendant Pfizer Inc. ("Defendant" or "Pfizer"), and files this Answer to
 2 Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

3 **I.**

4 **PRELIMINARY STATEMENT**

5 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
 6 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
 7 generally. Defendant may seek leave to amend this Answer when discovery reveals the specific
 8 time periods in which Plaintiff was prescribed and used Celebrex®.

9 **II.**

10 **ANSWER**

11 **Response to Allegations Regarding Parties**

12 1. Defendant is without knowledge or information sufficient to form a belief as to the truth
 13 of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
 14 whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that
 15 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
 16 prescribing information. Defendant denies that Celebrex® caused Plaintiff injury or damages
 17 and denies the remaining allegations in this paragraph of the Complaint.

18 2. Defendant admits that it is a Delaware corporation with its principal place of business in
 19 New York. Defendant admits that it is registered to do and does business in the State of
 20 Maryland. Defendant admits that it may be served through its registered agent. Defendant
 21 denies any wrongful conduct, denies having committed a tort in the State of Maryland, and
 22 denies the remaining allegations in this paragraph of the Complaint.

23 **Response to Allegation Regarding Jurisdiction**

24 3. Defendant is without knowledge or information sufficient to form a belief as to the truth
 25 of the allegations in this paragraph of the Complaint concerning Plaintiff's citizenship and the
 26 amount in controversy, and, therefore, denies the same. However, Defendant admits that
 27 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
 28 exclusive of interests and costs. Defendant denies the remaining allegations in this paragraph

of the Complaint.

Response to Allegation Regarding Venue

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®. Defendant admits that it does business in the State of Maryland. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

5. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States, including Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®. Defendant denies the remaining allegations in this paragraph of the Complaint.

6. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies that Celebrex® caused Plaintiff injury or damages and denies the remaining allegations in this paragraph of the Complaint.

7. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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1 of the Complaint.

2 8. Defendant admits that, during certain periods of time, it marketed and co-promoted
3 Celebrex® in the United States to be prescribed by healthcare providers who are by law
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
5 that it provided FDA-approved prescribing information regarding Celebrex®. Defendant
6 denies the remaining allegations in this paragraph of the Complaint.

7 9. Defendant admits that Celebrex® is in a class of drugs that is, at times, referred to as
8 non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that Celebrex® is a
9 prescription medication which is approved by the FDA for the following indications: (1) for
10 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
11 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
12 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
13 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
14 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
15 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
16 and older. Defendant denies the remaining allegations in this paragraph of the Complaint.

17 10. Defendant states that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
19 denies the remaining allegations in this paragraph of the Complaint.

20 11. Defendant states that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
25 of the Complaint.

26 12. Defendant states that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®.
3 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
4 damages, and denies the remaining allegations in this paragraph of the Complaint.

5 13. Defendant states that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendant states that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
10 of the Complaint.

11 14. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury
12 or damages, and denies the remaining allegations in this paragraph of the Complaint.

13 15. Defendant is without knowledge or information sufficient to form a belief as to the truth
14 of the allegations in this paragraph of the Complaint regarding Plaintiff's lifestyle, employment
15 history, medical condition, and whether Plaintiff used Celebrex®, and, therefore, denies the
16 same. Defendant states that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
18 denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations
19 in this paragraph of the Complaint.

20 16. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding Plaintiff's lifestyle, familial
22 relationships, medical condition, and whether Plaintiff used Celebrex®, and, therefore, denies
23 the same. Defendant states that Celebrex® was and is safe and effective when used in
24 accordance with its FDA-approved prescribing information. Defendant denies any wrongful
25 conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining
26 allegations in this paragraph of the Complaint.

27 17. Defendant states that this paragraph of the Complaint contains legal contentions to
28 which no response is required. To the extent that a response is deemed required, Defendant

1 states that the referenced Order speaks for itself and respectfully refer the Court to the Order for
2 its actual language and text. Any attempt to characterize the Order is denied. Defendant is
3 without knowledge or information sufficient to form a belief as to the truth of the allegations in
4 this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore,
5 denies the same. Defendant states that Celebrex® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendant denies any wrongful
7 conduct and denies the remaining allegations in this paragraph of the Complaint.

8 **Response to First Cause of Action: Negligence**

9 18. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
10 Complaint as if fully set forth herein.

11 19. Defendant admits that, during certain periods of time, it marketed and co-promoted
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
14 the remaining allegations in this paragraph of the Complaint.

15 20. Defendant states that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendant denies any wrongful conduct, denies that Celebrex® is unreasonably dangerous, and
20 denies the remaining allegations in this paragraph of the Complaint.

21 21. Defendant states that this paragraph of the Complaint contains legal contentions to
22 which no response is required. To the extent that a response is deemed required, Defendant
23 admits that it had duties as are imposed by law but denies having breached such duties.
24 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendant states that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or

1 damages, and denies the remaining allegations in this paragraph of the Complaint.

2 22. Defendant states that this paragraph of the Complaint contains legal contentions to
3 which no response is required. To the extent that a response is deemed required, Defendant
4 admits that it had duties as are imposed by law but denies having breached such duties.
5 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
6 FDA-approved prescribing information. Defendant states that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
10 damages, and denies the remaining allegations in this paragraph of the Complaint.

11 Answering the unnumbered paragraph following Paragraph 22 of the Complaint,
12 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
13 damages, and denies the remaining allegations in this paragraph of the Complaint.

14 **Response to Second Cause of Action: Strict Products Liability**

15 23. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
16 Complaint as if fully set forth herein.

17 24. Defendant states that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant denies any wrongful conduct, denies that Celebrex® is defective or unreasonably
22 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

23 25. Defendant states that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
28 remaining allegations in this paragraph of the Complaint.

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26. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the remaining allegations in this paragraph of the Complaint.

27. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the remaining allegations in this paragraph of the Complaint.

28. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the remaining allegations in this paragraph of the Complaint.

29. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

1 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
2 remaining allegations in this paragraph of the Complaint.

3 30. Defendant states that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendant states that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendant denies any wrongful conduct, denies that Celebrex® is defective, denies that
8 Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this
9 paragraph of the Complaint.

10 Answering the unnumbered paragraph following Paragraph 30 of the Complaint,
11 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
12 damages, and denies the remaining allegations in this paragraph of the Complaint.

13 **Response to Third Cause of Action: Fraud – Deceit by Concealment**

14 31. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 32. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
19 and effective when used in accordance with its FDA-approved prescribing information.
20 Defendant states that the potential effects of Celebrex® were and are adequately described in its
21 FDA-approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendant denies any wrongful conduct, denies that
23 Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this
24 paragraph of the Complaint.

25 Answering the unnumbered paragraph following Paragraph 32 of the Complaint,
26 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
27 damages, and denies the remaining allegations in this paragraph of the Complaint.

28

Response to Fourth Cause of Action: Negligent Misrepresentation

33. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

34. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

35. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

36. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 36 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

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Response to Fifth Cause of Action: Express Warranty for Goods

37. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

38. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 38 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Implied Warranties

A. Warranty of Merchantability

39. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

40. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used

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1 in accordance with its FDA-approved prescribing information. Defendant states that the
2 potential effects of Celebrex® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is
5 defective, and denies the remaining allegations in this paragraph of the Complaint.

6 41. Defendant states that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct, denies that Celebrex® is defective, denies that
11 Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this
12 paragraph of the Complaint.

13 **B. Warranty of Fitness**

14 42. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 43. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of
19 time, it marketed and co-promoted Celebrex® in the United States to be prescribed by
20 healthcare providers who are by law authorized to prescribe drugs in accordance with their
21 approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used
22 in accordance with its FDA-approved prescribing information. Defendant states that the
23 potential effects of Celebrex® were and are adequately described in its FDA-approved
24 prescribing information, which was at all times adequate and comported with applicable
25 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
26 allegations in this paragraph of the Complaint.

27 44. Defendant states that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
4 damages, and denies the remaining allegations in this paragraph of the Complaint.

5 Answering the unnumbered paragraph following Paragraph 44 of the Complaint,
6 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
7 damages, and denies the remaining allegations in this paragraph of the Complaint.

8 **Response to Seventh Cause of Action: Unjust Enrichment**

9 45. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
10 Complaint as if fully set forth herein.

11 46. Defendant is without knowledge or information sufficient to form a belief as to the truth
12 of the allegations in this paragraph of the Complaint, and, therefore, denies the same.
13 Defendant denies the remaining allegations in this paragraph of the Complaint.

14 47. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
17 and effective when used in accordance with its FDA-approved prescribing information.
18 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
19 of the Complaint.

20 48. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
23 and effective when used in accordance with its FDA-approved prescribing information.
24 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
25 of the Complaint.

26 Answering the unnumbered paragraph following Paragraph 48 of the Complaint,
27 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
28 damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Additional Prayers for Relief

49. Defendant states that this paragraph of the Complaint directs no allegations toward Defendant, and, therefore, no response is required.

50. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

51. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

52. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies the allegations in this paragraph of the Complaint.

53. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

54. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

1 **III.**

2 **GENERAL DENIAL**

3 Defendant denies all allegations and/or legal conclusions set forth in Plaintiff's
4 Complaint that have not been previously admitted, denied, or explained.

5 **IV.**

6 **AFFIRMATIVE DEFENSES**

7 Defendant reserves the right to rely upon any of the following or additional defenses to
8 claims asserted by Plaintiff to the extent that such defenses are supported by information
9 developed through discovery or evidence at trial. Defendant affirmatively shows that:

10 **First Defense**

11 1. The Complaint fails to state a claim upon which relief can be granted.

12 **Second Defense**

13 2. Celebrex® is a prescription medical product. The federal government has preempted
14 the field of law applicable to the labeling and warning of prescription medical products.
15 Defendant's labeling and warning of Celebrex® was at all times in compliance with applicable
16 federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon
17 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
18 and violate the Supremacy Clause of the United States Constitution.

19 **Third Defense**

20 3. At all relevant times, Defendant provided proper warnings, information and instructions
21 for the drug in accordance with generally recognized and prevailing standards in existence at
22 the time.

23 **Fourth Defense**

24 4. At all relevant times, Defendant's warnings and instructions with respect to the use of
25 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
26 knowledge at the time the drug was manufactured, marketed and distributed.

27 **Fifth Defense**

28 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pleaded in full bar of any liability as to
2 Defendant.

3 **Sixth Defense**

4 6. Plaintiff's action is barred by the statute of repose.

5 **Seventh Defense**

6 7. Plaintiff's claims against Defendant are barred to the extent Plaintiff was contributorily
7 negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any
8 recovery by Plaintiff should be diminished accordingly.

9 **Eighth Defense**

10 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
11 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part
12 of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable
13 in any way.

14 **Ninth Defense**

15 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
16 intervening causes for which Defendant cannot be liable.

17 **Tenth Defense**

18 10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were
19 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
20 of God.

21 **Eleventh Defense**

22 11. Defendant affirmatively denies that it violated any duty owed to Plaintiff.

23 **Twelfth Defense**

24 12. A manufacturer has no duty to warn patients or the general public of any risk,
25 contraindication, or adverse effect associated with the use of a prescription medical product.
26 Rather, the law requires that all such warnings and appropriate information be given to the
27 prescribing physician and the medical profession, which act as a "learned intermediary" in
28 determining the use of the product. Celebrex® is a prescription medical product, available only

1 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's
2 treating and prescribing physicians.

3 **Thirteenth Defense**

4 13. The product at issue was not in a defective condition or unreasonably dangerous at the
5 time it left the control of the manufacturer or seller.

6 **Fourteenth Defense**

7 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
8 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
9 the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

10 **Fifteenth Defense**

11 15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the
12 Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable
13 standard of care.

14 **Sixteenth Defense**

15 16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of
16 the product Celebrex® after the product left the control of Defendant and any liability of
17 Defendant is therefore barred.

18 **Seventeenth Defense**

19 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
20 Defendant.

21 **Eighteenth Defense**

22 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
23 conditions unrelated to Celebrex®.

24 **Nineteenth Defense**

25 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
26 the doctrine of assumption of the risk bars or diminishes any recovery.

27 **Twentieth Defense**

28 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are

preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to § 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical

1 product at issue “provides net benefits for a class of patients” within the meaning of Comment f
2 to § 6 of the Restatement (Third) of Torts: Products Liability.

3 **Twenty-eighth Defense**

4 28. Plaintiff’s claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
5 Products Liability.

6 **Twenty-ninth Defense**

7 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead
8 facts sufficient under the law to justify an award of punitive damages.

9 **Thirtieth Defense**

10 30. Defendant affirmatively avers that the imposition of punitive damages in this case
11 would violate Defendant’s rights to procedural due process under both the Fourteenth
12 Amendment of the United States Constitution and the Constitutions of the States of Maryland
13 and California, and would additionally violate Defendant’s rights to substantive due process
14 under the Fourteenth Amendment of the United States Constitution.

15 **Thirty-first Defense**

16 31. Plaintiff’s claims for punitive damages are barred, in whole or in part, by State of
17 Maryland law and by the Fifth and Fourteenth Amendments to the United States Constitution.

18 **Thirty-second Defense**

19 32. The imposition of punitive damages in this case would violate the First Amendment to
20 the United States Constitution.

21 **Thirty-third Defense**

22 33. Plaintiff’s punitive damage claims are preempted by federal law.

23 **Thirty-fourth Defense**

24 34. In the event that reliance was placed upon Defendant’s nonconformance to an express
25 representation, this action is barred as there was no reliance upon representations, if any, of
26 Defendant.

27 **Thirty-fifth Defense**

28 35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance

1 to any express representation.

2 **Thirty-sixth Defense**

3 36. To the extent that Plaintiff's claims are based on a theory providing for liability without
4 proof of causation, the claims violate Defendant's rights under the United States Constitution.

5 **Thirty-seventh Defense**

6 37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and
7 labeling with respect to the subject pharmaceutical products were not false or misleading and,
8 therefore, constitute protected commercial speech under the applicable provisions of the United
9 States Constitution.

10 **Thirty-eighth Defense**

11 38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
12 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
13 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
14 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
15 Amendment of the United States Constitution, the Commerce Clause of the United States
16 Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable
17 provisions of the Constitutions of the States of Maryland and California. Any law, statute, or
18 other authority purporting to permit the recovery of punitive damages in this case is
19 unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks
20 constitutionally sufficient standards to guide and restrain the jury's discretion in determining
21 whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that
22 it failed to provide adequate advance notice as to what conduct will result in punitive damages;
23 (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied
24 with applicable law, or conduct that was not directed, or did not proximately cause harm, to
25 Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and
26 proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory
27 damages, if any; (5) permits jury consideration of net worth or other financial information
28 relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial

1 court in post-verdict review of any punitive damages awards; (7) lacks constitutionally
2 sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to
3 satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v.*
4 *Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443
5 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto*
6 *Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

7 **Thirty-ninth Defense**

8 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
9 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
10 instructions with respect to the product's use in the package insert and other literature, and
11 conformed to the generally recognized, reasonably available, and reliable state of the
12 knowledge at the time the product was marketed.

13 **Fortieth Defense**

14 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
15 tested, manufactured, and labeled in accordance with the state-of-the-art industry standards
16 existing at the time of the sale.

17 **Forty-first Defense**

18 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
19 and belief, such injuries and losses were caused by the actions of persons not having real or
20 apparent authority to take said actions on behalf of Defendant and over whom Defendant had
21 no control and for whom Defendant may not be held accountable.

22 **Forty-second Defense**

23 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
24 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
25 intended, and was distributed with adequate and sufficient warnings.

26 **Forty-third Defense**

27 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
28 waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions, or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of

responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of Plaintiff and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendant states on information and belief that any injuries, losses, or damages suffered

1 by Plaintiff was proximately caused, in whole or in part, by the negligence or other actionable
 2 conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against
 3 Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

4 **Fifty-seventh Defense**

5 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
 6 Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil
 7 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
 8 damages is also barred under California Civil Code § 3294(b).

9 **Fifty-eighth Defense**

10 58. Defendant reserves the right to supplement its assertion of defenses as it continues with
 11 its factual investigation of Plaintiff's claims.

12 **V.**

13 **JURY DEMAND**

14 Defendant hereby demands a trial by jury of all the facts and issue in this case pursuant
 15 to Federal Rule of Civil Procedure 38(b).

16 **VI.**

17 **PRAYER**

18 WHEREFORE, Defendant prays for judgment as follows:

- 19 1. That Plaintiff takes nothing from Defendant by reason of the Complaint;
- 20 2. That the Complaint be dismissed;
- 21 3. That Defendant be awarded its costs for this lawsuit;
- 22 4. That the trier of fact determine what percentage of the combined fault or other liability
 23 of all persons whose fault or other liability proximately caused Plaintiff's alleged
 24 injuries, losses or damages is attributable to each person;
- 25 5. That any judgment for damages against Defendant in favor of Plaintiff be no greater
 26 than an amount which equals Plaintiff's proportionate share, if any, of the total fault or
 27 other liability which proximately caused Plaintiff's injuries and damages; and
- 28 6. That Defendant has such other and further relief as the Court deems appropriate.

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June 26, 2008

GORDON & REES LLP

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JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

June 26, 2008

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